BACKGROUND PAPER ON TUSKEGEE STUDY

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Introduction

In the late 1920's and early 1930's, surveys in rural areas of the South revealed a high incidence of syphilis among blacks, and it was determined that many of those infected remained untreated. Because of the lack of knowledge of the pathogenesis of syphilis, a long-term study of untreated syphilis was considered desirable in establishing a more knowledgeable syphilis control program.

"A prospective study was begun late in 1932 in Macon County, Alabama, a rural area with a static population and a high rate of untreated syphilis. An untreated population such as this offered an unusual opportunity to follow and study the disease over a long period of time. In 1932, a total of 26 percent of the male population tested, who were 25 years of age or older, were serologically reactive for syphilis by at least two tests, usually on two occasions. The original study group was composed of 399 of these men who had received no therapy and who gave historical and laboratory evidence of syphilis which had progressed beyond the infectious stages. A total of 201 men comparable in age and environment and judged by serology, history, and physical examination to be free of syphilis were selected to be the control group."[1]

Since its inception, the study has been of great scientific interest to the medical community, has been widely discussed at medical meetings, and has been the subject of not less than 15[1-15] papers published in the American medical literature.

Results

The first published findings in 1936 by Vonderlehr et al.[2] showed after infection of 15 years' duration only one-fourth of the untreated syphilitics were normal and that most of the abnormal findings were in the cardiovascular system. Morbidity was noted to be approximately fourfold greater in the cardiovascular, central nervous, and bone and joint systems of untreated syphilitics under age 40 than in the controls of the same age.

In 1952, Rosahn[15] published comparisons of 1946 data from the Tuskegee Study and from a second public health survey[16] published in 1937 involving both white and black syphilis patients under treatment or observation for 6 months or more in five syphilis clinics in the pre-penicillin era. Although a comparison of this black clinic population with the Tuskegee syphilitic population suffers from several biases, the clinic population, many of whom were presumably treated, actually had a greater average decrease in life expectancy (30.5 percent) than did the Tuskegee syphilitic (16.1 percent).

Studies by Shafer et al. published in 1954[7] showed that male untreated syphilitic patients under the age of 50 in the Tuskegee Study were experiencing an average reduction in life expectancy of some 17 percent over that of non-syphilitic controls. In patients between 50 and 65, the reduction was some 14 percent and for those over 65, approximately 6 percent

Reporting on the thirtieth year of observation (1963), Rockwell et al.[1] stated that of the original syphilitics, 59 percent were dead, 21 percent alive, and 20 percent were lost to follow up, while 45 percent of the controls were dead, 34 percent alive, and 20 percent lost to follow up. A comparison of the life expectancy in the syphilitic and control groups was not reported at this time.

In 1971 in the most recent study, Caldwell et al.,[14] reported on the incidence of aortic regurgitation in the study group. Among 76 survivors initially in the untreated syphilis group, clinical findings of aortic regurgitation were noted in two. Among 51 survivors in the control group, aortic regurgitation was again noted in two. Some 70 patients (belonging to both the syphilitic and control groups) were lost to follow up. Among 140 syphilitics on whom autopsies were performed, 44 percent had evidence of aoritis, while among 54 controls 15 percent had such evidence, a difference significant at the 0.005 level. A comparison of the life expectancy in the syphilitic and control groups was not reported at this time.

Treatment for Syphilitic Patients

Until the advent of penicillin, the treatment for syphilis required the injection of toxic substances such as mercury and arsenic. Many physicians were confident that the risk of treatment exceeded the risk of disease.

In 1943, Dr. John Mahoney reported the first cures of primary and secondary syphilis with penicillin. When this drug first became widely available (1946-47), the question naturally arose concerning the advisability of

we have no papers on this

treating all of those in the syphilitic group. A decision was made at that time not to recommend treatment because (1) no data was available on the efficacy of penicillin treatment in late syphilis and (2) the short and long term toxic effects of this drug had not as yet been well documented. The judgment was made that the possible risks to the patients from treatment outweighted their risks from the disease. Reassessments of the advisability of treating all the Tuskegee Study syphilitics have been made periodically since 1946 (the last being made in 1969), and the conclusions have remained the same: the benefits of non-treatment have been judged to outweigh the benefits conferred by such treatment.

Although it will not be possible to recreate the milieu of social and scientific opinion in which the decisions not to treat the syphilitic persons in the group have been taken, it is appropriate to undertake a review of the case records to reconstruct the risks and benefits from treatment both in the light of current knowledge and in the light of knowledge presumed to be available to the various decision makers of each juncture in the study, including the present. (It should be noted that of the 76 syphilitic patients now known to be living, 75 have at some juncture in the past received antibiotic therapy, and in approximately 30 percent such therapy is thought to have been adequate for the cure of syphilis.)

Conclusion

Although this study has been widely publicized in professional circles since its inception, and although persons in the study group were informed they had syphilis, were informed that they could request and receive syphilis treatment at any time, and were treated appropriately for other medical conditions as they arose, it has been necessary throughout the course of the study to make judgments whether to recommend to all the syphilitic patients that they receive treatment. At no time in the course of the study has treatment been without risk, and the judgment has been consistently made that this risk has outweighted the benefits anticipated from treatment.

Administrative Details Concerning Tuskegee Study

Participation in the study by both syphilitic and non-syphilitic persons was voluntary. The syphilitic group was informed that they had syphilis, and informed that they would be treated for the disease if they so requested. (Because of the level of comprehension in this population group, this information may have been translated into a simple statement that the person had "bad blood"--a common synonym for syphilis--and could be treated if he desired.)

A public health nurse has been provided by the Public Health Service to the Macon County Health Department from 1932 to the present to assist in providing health care and follow up to the study group. Since 1932, the study group has received periodic physical and laboratory examinations (including blood tests), and members have been treated or referred for appropriate care when abnormalities other than positive serologies were noted. Since 1968, such examinations have been given every 2 years.

The study has received support from several groups. The Milbank Memorial Fund provides funds for pathological examinations and a burial allowance for those autopsied. (The allowance was $50 for many years, and has been increased to $100 within the last 2 years. About half the persons who have died have been autopsied, with the percentage of autopsies being approximately the same in the syphilitic and control groups.) The Tuskegee Institute assisted with the administration of the Milbank funds, and the Institute's hospital has provided care to persons referred from the study group. The Veterans Administration Hospital of Tuskegee also provided care for referred patients, and assisted with autopsies. The Macon County Health Department has been intimately involved with the follow up of study participants, and the Macon County Medical Society has been fully informed concerning the study.

The records reviewed to date present no evidence that a formal review of this study by an outside advisory group was undertaken prior to 1969, when such a group was convened by the Center for Disease Control. This group recommended that (1) the study be continued and (2) no treatment for syphilis be given unless evidence for active disease was present.

Where is a copy of this study?

References

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